Medtronic

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm 1-23, 12420 Parklawn Drive
Rockville, MD 20857

RE: CITIZEN PETITION
REQUEST FOR AN EXEMPTION

The undersigned submits this petition under 21 CFR §898.14 to request the Commissioner of Food and Drugs ("CFD") to exempt the devices described below from the Performance Standard of 21 CFR Part 898 Performance Standard For Electrode Lead Wires and Patient Cables (hereafter "Performance Standard").

I. Description Of Products.

This petition relates to new models of Medtronic catheter-introduced temporary transvenous pacing leads which are classified as Class II devices under 21 CFR §870.3680(a). The first example of such a lead is Medtronic Model 6416, which is cleared for marketing in the U.S. A copy of a brochure entitled "Implant Guidelines," attached as Exhibit A, explains the product and its use.

II. Use Of Temporary Pacing Leads.

A temporary pacing lead is used during and shortly after surgery for providing a means to pace the heart should there be complications of surgery which require temporary pacing. Temporary pacing leads are also used when temporary pacing serves as definitive therapy for transient bradyarrhythmia or to support patient with sustained bradycardia until a permanent pacemaker system is implanted. One type of such lead is introduced intravenously; that is, either a surgical cutdown is done to locate a vein, or a small incision is made to insert an introducer into a vein. Then the pacing lead is inserted in the vein.
Because they are introduced through the vein into the heart, traditional temporary leads must be stiff enough to transmit both axial and rotational force from the proximal end to the distal end while pushing the lead into place. This requirement resulted in stiff, large-diameter leads. There are certain handling characteristics inherent in such leads upon which the Model 6416 is designed to improve. Such characteristics include the following:

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1. A larger lead is inherently more difficult to pass through the vein, especially in patients with small veins or tortuous vein anatomy. It also makes it more difficult to pass a second lead so that both chambers of the heart can be paced. Dual-chamber temporary pacing is aided by a small-diameter lead.

2. Unless proper care is taken when introducing the stiff lead, there is the possibility of applying too much pressure at the tip against heart tissue. This can result in perforation of the heart tissue.

3. Traditional leads are basically kept in place by being lodged in the apex of the heart. Pressure is exerted on the proximal end to put a bend in the lead within the heart, forcing the distal tip against heart tissue. Then, the proximal end is sutured to tissue near the implant site to keep the pressure on the tip. Anecdotal evidence from the clinical study shows that these stiffer leads are more likely to dislodge than a Model 6416. This dislodgment results in loss of electrical conductivity, which is known as loss of capture.

4. Leads with stiffer bodies can also cause patient discomfort at the wound site where the lead exits the body. Traditional leads must be sutured down at this site to maintain forward pressure against the ventricle wall. A stiffer lead body can transmit patient movements more effectively to the wound site, causing pain and skin irritation for the patient.

5. Traditional leads with stiffer bodies make atrial use difficult, if not impossible. It is difficult to position the lead to exert and maintain a forward pressure against the atrium's wall. A typical lead can be lodged only in the atrial appendage. The friction resulting in transferred motion between the arterial vessels and the lead often causes dislodgment. In dual-chamber uses, two leads would rub against each other, causing dislodgment.

The new family of Medtronic leads, led by the Model 6416, attempts to ameliorate these handling issues by allowing introduction in an entirely different manner. These leads are introduced through a guide catheter. The guide catheter provides the stiffness required for steerability and pushability. Once the lead is placed and fixed within the heart, the guide catheter is removed, leaving the small-diameter, flexible lead in place.

Introduction of a catheter-introduced lead is shown in Attachment A. The lead is inserted in a guide catheter. The catheter is introduced into a vein in much the same manner as other types of transvenous pacing leads. On this model, the lead is then screwed into the heart to provide positive

fixation. The lead is then electrically tested. After electrical contact with the heart is verified, the catheter is withdrawn over the lead and the lead is connected to the temporary pacemaker.

It is this last step that is critical in attempting to comply with the Performance Standard. In order to fit through the guide catheter, the electrical contacts on the proximal end of the pacing lead must be very small. The contacts of the Model 6416 are shown on the next to the last page of Attachment A. Attachment B is a drawing which illustrates the interaction of the connector pins and the guide catheter. Fig. 1 shows the lead A inside of guide catheter B. Guide catheter B is a 6 French catheter with an inner diameter of .064 inches nominal. Conductor wires C and D extend from the body of lead A. The wires C and D each have a connector pin E and F at their ends. Note that, in order to fit within the lumen of guide catheter B, the pins E and F cannot be side by side. Their position is offset by making wires C and D of different lengths so that pins E and F are longitudinally spaced within guide catheter B. In this manner, the smallest possible guide catheter B may be used for introduction.

Obviously pins E and F must be of small diameter in order to accomplish this design. These pins cannot be electrically shielded to comply with the Performance Standard and still fit within a guiding catheter. It is for this reason that Medtronic is seeking relief from the Performance Standard. It is believed that the benefits to the patient and the reduction in risks possible through this design are greater than the risk of electrical shock associated with the pins. It should be noted that notified bodies that grant the CE mark recognized the infeasibility of applying subclause 56.3 c) of IEC 60601-1 and used other safety data in granting the CE mark for this device.

In summary, there are many benefits to implantation through a guide catheter. This technique allows the use of a slimmer, less stiff lead. Two leads can be introduced into one vein, allowing dual-chamber pacing. This design has positive fixation, which removes the requirement that the lead apply pressure against the heart wall, as in prior leads. There is less dislodgment. All of these patient benefits may be lost if the concept of introduction by catheter is prevented by the Performance Standard.

IV. Reasons That Mitigate The Risk.

Temporary pacing leads are used in the surgical sterile area or in the intensive care unit during recovery immediately after surgery. Temporary pacing leads are also used in catheterization laboratories and emergency treatment areas. Obviously there are no AC mains in the sterile area and the personnel within these areas are all highly trained professionals who are not going to accidentally plug the pacing lead into a mains outlet. After introduction, the exposed lead body is either immediately inserted into a patient cable or external pacemaker, or is coiled up and taped to the patient until it is needed to provide temporary pacing.

These patients do not leave the hospital with a temporary pacing lead in place.

The same international standard which is incorporated into the Performance Standard was considered by the Notified Body when granting the CE mark for the Model 6416. It was determined by the Notified Body that the standard should not be applied because it was not possible to pass a touch-safe tip through the catheter. Therefore, other safety data was used instead of the standard.

V. Scope Of Petition.

Temporary pacing leads have been used for 20 years without any reported instance of patient injury due to improper insertion of the pin connector into a mains or a power cable connected to a mains. Therefore, applicant seeks an exemption for all Medtronic catheter-introduced pacing leads, rather than providing a specific model number requiring the agency to go through an exemption for successive models of this design. Medtronic seeks exemption for all its temporary pacing leads which are introduced through a guide catheter which is removed over the pacing lead body.

VI. Environmental Impact.

There is no environmental impact statement needed because this Petition, as an exemption from a standard, is automatically exempt under 21 CFR §25.24(e)(3).

VII. Certification.

The undersigned certifies that, to the best knowledge of the undersigned, this petition includes all information and views on which the Petitioner relies and includes representative that information known to Petitioner which are unfavorable to the petition.

Yours truly,

MEDTRONIC, INC.

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